OCT 1 9 2000

K002479

510(k) SUMMARY

Cousin Biotech's Biomesh® P1 and Biomesh® Plug and Patch

Sponsor's Name, Address, Telephone Number, Contact Person and Date Prepared

Christèle Nardo
Cousin Biotech S.A.S.
8, rue Abbé Bonpain
B.P. 39 F-59117
Wervicq-Sud
France

Date Prepared: August 11, 2000

Name of Device and Name/Address of Sponsor

Biomesh® P1 and Biomesh® Plug and Patch

Common or Usual Name

Surgical Mesh

Classification Name

Surgical Mesh

Predicate Devices

The Biomesh® P1 and Biomesh® Plug and Patch surgical meshes are substantially equivalent to: (1) Sofradim Production's Parietex® and Parietene® meshes; (2) Ethicon, Inc.'s Prolene mesh; (3) United States Surgical Corporation's SurgiPro Mesh Plug; (4) Bard-Davol's Marlex mesh; and (5) Shelhigh, Inc.'s No-React® Tissue Repair mesh.

Intended Use/Indications

The Biomesh® P1 and Biomesh® Plug and Patch surgical meshes, Sofradim Production's Parietex® and Parietene® meshes, Ethicon, Inc.'s Prolene mesh U.S.S.C.'s Surgipro mesh and plug, Bard-Davol's Marlex PerFix Plug mesh, and Shelhigh, Inc.'s No-React® Tissue Repair mesh are intended to be used for the reinforcement of tissue during surgical repair. Thus, the Biomesh® P1 and Biomesh® Plug and Patch meshes and all of the predicates have the same intended use.

The Biomesh® P1 meshes are specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical, and incisional hernias; rectal, vaginal and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair. The Biomesh® Plug and Patch meshes are specifically indicated for open surgery for the repair of direct or indirect inguinal and femoral hernias, parietal reinforcement of tissues, and abdominal wall repair. The Biomesh P1 and Plug and Patch have the same indications as a combination of the predicate devices.

Technological Characteristics

The Biomesh® P1 and Biomesh® Plug and Patch meshes are substantially equivalent to the other currently marketed meshes, which are referenced above.

The Biomesh® P1 mesh is square shaped and consists of nonopenworked monofilament stitches. Biomesh® P1 is square shaped and consists of nonopenworked monofilament stitches while the Biomesh® P1 is square shaped and consists of nonopenworked monofilament stitches. The Biomesh® Plug and Patch consists of a nonopenworked monofilament stitched conical shaped plug that contains an inner mesh filler and a keyhole shaped mesh. The keyhole slit shaped mesh, which is flat, is the patch. The plug's inner mesh filler stiffens the plug when it is compressed by the tie.

The Biomesh® P1 and Plug and Patch have the same intended use and the indications for use, as a combination of the predicate devices. The Biomesh P1 and Plug and Patch also have very similar principles of operation and technological characteristics as the predicate devices. Any minor technological differences in the P1 and Plug and Patch's size or shape do not raise any new question of safety or effectiveness. Bench testing confirms that the Biomesh mesh meets its specifications. Therefore, these meshes are substantially equivalent.

Performance Data

In accordance with FDA's "*Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh*" (March 2, 1999) ("Surgical Mesh Guidance"), the Company performed bench testing to determine the Biomesh® P1 and Biomesh® Plug and Patch's mesh thickness, mesh weave characteristics, pore size, mesh density, tensile strength, mesh stiffness, suture pullout strength, burst strength, and tear resistance. In addition, the Company tested residual levels of manufacturing reagents, and residual levels of heavy metals on the final product. These tests show that the meshes meet the Company's specifications. Stability testing showed that the meshes remained stable for at least 18 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Cousin Biotech S.A.S.
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K002479
Trade Name: Biomesh® P1 and Biomesh® Plug and Patch
Regulatory Class: II
Product Code: FTL
Dated: August 11, 2000
Received: August 11, 2000

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002479

Device Name: **Biomesh® P1 and Biomesh® Plug and Patch**

Indications for Use:

The Biomesh® P1 and Biomesh® Plug and Patch meshes are surgical meshes that are intended to be used for the reinforcement of tissue during surgical repair. The Biomesh® P1 meshes are specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical, and incisional hernias; rectal, vaginal and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair. The Biomesh® Plug and Patch meshes are specifically indicated for open surgery for the repair of direct or indirect inguinal and femoral hernias, parietal reinforcement of tissues, and abdominal wall repair.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002479

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)